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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,233

06/26/2006

Hiroshi Koyano

KOYANO 1

1954

1444 7590 03/03/2009
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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,233	Applicant(s) KOYANO ET AL.	
	Examiner Taofiq A. Solola	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>na</u> . | 6) <input type="checkbox"/> Other: _____ |

This Office action supersedes the previous communication.

Claims 1-17, are pending in this application.

DETAILED ACTION

Election/Restriction

Claims 1-17 are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that □special technical features□ mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

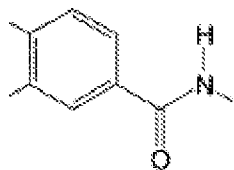
I. Claims 1-12, in part, drawn to compounds of formula II, wherein Q1 or Q2 is O, S, or N, and L is one (only) of the formulae in claim 1, classifiable in classes 540 and numerous subclasses.

II. Claims 1-12, in part, drawn to compounds of formula II, wherein any one of A1-A5 is N, and L is one (only) of the formulae in claim 1, classifiable in classes 544, 546 and numerous subclasses.

III. Claims 1-12, in part, drawn to compounds of formula II, wherein A1-Q1-Q2-ring has no heteroatoms, classifiable in classes 564 and numerous subclasses.

IV. Claim 13-17, drawn to various methods of using compound of formula II, classifiable in class 514 and numerous subclasses.

1. In the instant inventions, the only structural element shared by groups I-IV is



. However, the structure is not novel. See WO 97/03967. Therefore, under PCT Rules 13.1 and 13.2, the structure does not constitute a corresponding special technical feature among the groups.

2. Each of the different methods of use of the inventions set forth in Group III is unrelated to the others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use of the compounds are unrelated because the patient populations being treated are different.

If applicant elects invention of group IV or in a rejoinder thereof applicant must elect a specific disease and group IV would be examined commensurate in scope therewith. Applicant must also one of groups I-III, and group IV would be examined commensurate in scope therewith.

3. In an election of any of Groups I-IV, an election of a single compound (or set of compounds) is further required including an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must

select a single substituent of R1, for example OH or aryl, and each subsequent variable position.

In the instant case, Applicant must elect one representative for each of A1-A5, Q1-Q2, X1-X5, L, Y and Z in formula II, and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic so as to define a species, and the species must be disclosed in the specification. Part of the species corresponding to each substituent in formula II must be identified.

All compounds falling outside the class(es) and subclass(es) of the selected compounds and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R.

1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Response to Restriction

The election of group III with traverse in the paper filed 12/29/08 is hereby acknowledged. The traversal is on the basis that, the claims are generic, embracing groups I-IV, that applicant is entitled to his/her invention, and the USPTO cannot legally force applicant to claim less than applicant's generic invention if the claims are not rejected, citing *In re Weber*, 198 USPQ 328, 331 (CCPA 1978). This is not persuasive because, applicant is not denied the chance to claim his/her invention since restricted claims may be claimed in a divisional application. The decision in *Weber* is applicable except where there is lack of unity of invention

as in the instant case. *In re Harnisch*, 206 USPQ 300 (CCPA 1980), *Ex Parte Hozumi*, (Bd. Pat. App. & Int. (1984). See reason for lack of unity above. Since the groups belong to different classifications, and a prior art anticipating one group would not render other groups obvious, they are independent and distinct. Also, it would be a serious burden on the Examiner to examine all the inventions because all classes and subclasses must be searched. The invention of group III will be rejoined as set forth in the Restriction Requirement.

Applicant fails to elect one of the formulae represented by L as required in the restriction but, elects example 2-2-48, wherein L is ethylene and therefore, ethylene is deemed elected by applicant.

The restriction is deemed proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The term "prodrug" is not defined in the specification so as to ascertain the structures of the compounds that are included and/or excluded by the term. By deleting the term the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The structures of the compounds embraced by "prodrug" are not defined in the claims so as to determine the metes and bounds of the claims. Therefore, the claims are indefinite. See the Examiner's suggestion above.

The presence of "[Formula 1]", claim 1, line 4, "[Formula 2]", page 7, and "[Formula 3]", claim 2, line 5, render the claims confusing and therefore indefinite. BY deleting them the rejection would be overcome.

Claim 1 as written, is not clear, confusing and therefore indefinite. It is suggested that applicant use combination of colon and semicolon in rewriting the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Heesemann, J. Ame. Chem. soc. (1980), Vol. 102(7), pp. 2167-76, and Huth, et al., WO 2001081311 A1, individually.

The prior arts disclose compounds in the attached abstract which are deemed prodrugs of the instant claimed compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumura, Nippon Kagaku Zasshi (1961), Vol. 82, pp. 623-6.

Applicant claims compound of formula II and composition thereof.

Determination of the scope and content of the prior art (MPEP §2141.01)

Matsumura teaches the compound in the attached abstract and composition thereof.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of the prior art is that applicant claims alkyl instead of H by the prior art at position Y.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, H and alkyl are art recognized equivalents. *In re Lincoln*, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

Therefore, the instant invention is prima facie obvious from the teaching of the prior art. One of ordinary skill in the art would have known to replace H with alkyl at the time the instant invention was made. The motivation is from the knowing that H and alkyl are equivalents. By

showing unexpected results through a side-by-side comparison using the instant utility (angiogenesis inhibition) the rejection would be overcome.

Objection

Claims 1-12 are objected to for containing non-elected inventions. The claims must be amended according to applicant's election, wherein A1 is C-X1, Q1 is -A2=A3-, Q2 is -A4=A5-, A2 is C-X2, A3 is C-X3, A4 is C-X4, A5 is C-X5, L is ethylene, Y and Z are as defined in the claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

February 27, 2009

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